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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,371	12/13/2006	Stephane Paul	1032751-000123	7331

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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

NOTIFICATION DATE	DELIVERY MODE
10/06/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/565,371	PAUL, STEPHANE	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. This application is a 371 of PCT/EP04/08114. For applications filed under 371, PCT rules for lack of unity apply.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups I-19. Claims 1-16, 30, are drawn to a fusion protein comprising two different cytokines.

Groups 20-38. Claims 17-25, 28, 29, 45, 47, are drawn to a nucleic acid encoding a fusion protein comprising two different cytokines, a vector, a host cell and a method for producing the fusion protein.

Groups 39-57. Claims 26-27, 42-44, 46, are drawn to an infectious viral particle comprising a nucleic acid molecule encoding a fusion protein comprising two different cytokines and a process for producing an infectious viral particle.

Groups 58-76. Claims 31-41, drawn to a method for the preparation of a drug intended for treating cancer comprising administering a fusion protein comprising two different cytokines.

Groups 77-95. Claims 31-41, drawn to a method for the preparation of a drug intended for preventing cancer comprising administering a fusion protein comprising two different cytokines.

Groups 96-115. Claims 31, 33, 48, drawn to a method for the preparation of a drug intended for treating cancer comprising administering a vector encoding a fusion protein comprising two different cytokines.

Groups 116-134. Claims 31, 33, 48, drawn to a method for the preparation of a drug intended for preventing cancer comprising administering a vector encoding a fusion protein comprising two different cytokines.

Groups 135-153. Claims 31, 33, 49, 52, drawn to a method for the preparation of a drug intended for treating cancer comprising administering an infectious viral particle comprising a nucleic acid encoding a fusion protein comprising two different cytokines.

Groups 154-172. Claims 31, 33, 49, 52, drawn to a method for the preparation of a drug intended for preventing cancer comprising administering an infectious viral particle comprising a nucleic acid encoding a fusion protein comprising two different cytokines.

Groups 173-191. Claims 31, 33, 50, 53, drawn to a method for the preparation of a drug intended for treating cancer comprising administering a host cell comprising a nucleic acid encoding a fusion protein comprising two different cytokines.

Groups 192-210. Claims 31, 33, 50, 53, drawn to a method for the preparation of a drug intended for preventing cancer comprising administering a host cell comprising a nucleic acid encoding a fusion protein comprising two different cytokines.

Groups 211-229. Claims 31-41, drawn to a method for the preparation of a drug intended for treating an infectious disease comprising administering a fusion protein comprising two different cytokines.

Groups 230-248. Claims 31-41, drawn to a method for the preparation of a drug intended for preventing an infectious disease comprising administering a fusion protein comprising two different cytokines.

Groups 249-267. Claims 31, 33, 48, drawn to a method for the preparation of a drug intended for treating an infectious disease comprising administering a vector encoding a fusion protein comprising two different cytokines.

Groups 268-286. Claims 31, 33, 48, drawn to a method for the preparation of a drug intended for preventing an infectious disease comprising administering a vector encoding a fusion protein comprising two different cytokines.

Groups 287-305. Claims 31, 33, 49, 52, drawn to a method for the preparation of a drug intended for treating an infectious disease comprising administering an infectious viral particle comprising a nucleic acid encoding a fusion protein comprising two different cytokines.

Groups 306-324. Claims 31, 33, 49, 52, drawn to a method for the preparation of a drug intended for preventing an infectious disease comprising administering an infectious viral particle comprising a nucleic acid encoding a fusion protein comprising two different cytokines.

Groups 325-343. Claims 31, 33, 50, 53, drawn to a method for the preparation of a drug intended for treating an infectious disease comprising administering a host cell comprising a nucleic acid encoding a fusion protein comprising two different cytokines.

Groups 344-362. Claims 31, 33, 50, 53, drawn to a method for the preparation of a drug intended for preventing an infectious disease comprising administering a host cell comprising a nucleic acid encoding a fusion protein comprising two different cytokines.

NOTE: Should any one of the Groups from 1- 362 be elected, Applicant is required to select one SEQ ID NO selected from SEQ ID NO:1-19 (one amino acid sequence SEQ ID NO) Once one polypeptides sequence of specific SEQ ID NO is selected, all other sequences will be withdrawn from consideration.

The inventions listed as Groups I-362 do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding special technical feature for the following reasons:

The PCT rules define a special technical feature as a feature, which defines a contribution over the prior art. The first claimed invention fails to recite such a feature, since EP 0158198 (Takeda Chemical Industries, Ltd.) teaches a fusion polypeptide comprising the amino acid sequence of human interferon and the amino acid sequence of human IL-2 (see abstract). The fusion protein of the reference meets the limitations of a fusion protein of Group I. Since the first claimed invention lacks a special technical feature, the other claimed inventions cannot share a special technical feature with the first claimed invention.

The inventions of Groups 20-28 and 39-57 are patentably distinct from the products of Groups 1-19, because the products of Groups 1-19 are structurally and functionally different from the products of Groups 20-28 and 39-57. Similarly, the inventions of Groups 1-19 are patentably distinct from the method of Groups 96-115, 116-134, 135-153, 154-172, 173-191, 192-210, 249-267, 268-286, 287-305, 306-324, 325-343, 344-362 because the products of Groups 1-19 because the products of inventions 1-19 can be used in methods that are materially different from the methods of Groups 96-115, 116-134, 135-153, 154-172, 173-191, 192-210, 249-267, 268-286, 287-305, 306-324, 325-343, 344-362, such as in the production of antibodies.

The inventions of Groups 1-19 are patentably distinct from the method of Groups 20-38 because the products of Groups 1-19 can be synthesized by a materially different method, such as by chemical synthesis. The inventions of Groups 20-38 are patentably distinct from the methods of Groups 58-95, 135-248, 287-363, because the products of Groups 20-38 can be used in methods that are materially different from the methods of Groups 58-95, 135-248, 287-363, such as in hybridization experiments as a probe. The methods of Groups 58-362 are patentably distinct from each other because each method requires, starting materials, patient populations, method steps and method goals not required by the other, and the search of all methods in one patent application would result in an undue search burden.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Election of species

4. This application contains claims directed to the following patentably distinct species of effector cells of the claimed invention:

If any one of Groups 1-19 is elected Applicants are required to elect one of the following species of effector cells selected from:

macrophages, dendritic cells, NK cells and NKT cells.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 5-16, 30, are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Rejoinder under *In re Ochiai and In re Brouwer*

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Prema Mertz/
Primary Examiner
Art Unit 1646